In re New England Compounding Pharmacy, Inc. Prods. Liab. Litig.
No. 1:13-md-02419-RWZ

U.S. Food & Drug Admin. Mot. Prot. Order

Ex. A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC., PRODUCTS LIABILITY LITIGATION	Court No.: 13-md-2419-RWZ

DECLARATION OF UNITED STATES ATTORNEY CARMEN M. ORTIZ

Pursuant to Title 28, United States Code, Section 1746, I, Carmen M. Ortiz, declare as follows:

1. I am the United States Attorney for the District of Massachusetts, and have served in this position since 2009.

2. As United States Attorney, I lead the United States Attorney's Office ("USAO") and oversee the work of approximately 120 Assistant United States Attorneys ("AUSAs"). The USAO represents the United States in federal criminal and civil matters within the District of Massachusetts.

3. This declaration is based on my personal knowledge of the USAO's criminal investigation, and information supplied to me in my official capacity as the United States Attorney for the District of Massachusetts.

The NECC Criminal Investigation

4. Beginning in October 2012, the USAO commenced a criminal investigation of New England Compounding Pharmacy, Inc., doing business as New England Compounding Center ("NECC"). The criminal investigation was a result of the nationwide outbreak of fungal meningitis. The U.S. Centers for Disease Control and Prevention ("CDC") has reported that 751 patients in 20 states were diagnosed with a fungal infection after receiving injections of NECC's

methylprednisolone acetate. Of those 751 patients, the CDC reported that 64 patients in nine states died.

5. The NECC criminal investigation is one of the highest priorities of the USAO; in fact, it is one of the most significant federal prosecutions currently ongoing in the United States. The prosecution is led by a team of AUSAs in the USAO and attorneys from the Consumer Protection Branch of the Department of Justice ("DOJ"). The investigation is being conducted by the U.S. Food and Drug Administration's Office of Criminal Investigations ("FDA-OCI"); the Federal Bureau of Investigation; the Department of Veterans Affairs, Office of Inspector General; the Department of Defense, Defense Criminal Investigative Service; and the United States Postal Inspection Service.

6. As part of the criminal investigation, in October 2012, FDA-OCI agents executed two search warrants at NECC, located at 697 Waverly Street, in Framingham, Massachusetts.[1] As a result of the warrants, FDA-OCI agents seized more than 760,000 pages of documents from NECC. In addition, FDA-OCI agents seized electronic media containing NECC's e-mail, financial, and operational records. FDA-OCI agents also seized numerous physical items from NECC, including compounded drugs in bulk form; compounded drugs packaged in vials, syringes, bottles, and bags; drug ingredients; lab materials; lab equipment; packaging materials; and surveillance videos.

7. As part of the criminal investigation, AUSAs and law enforcement agents conducted a thorough review of NECC's regulatory history, including its previous inspections by the FDA and the Massachusetts Board of Registration in Pharmacy, and NECC's representations about its business to regulators throughout its years of operation.

[1] The Honorable Leo T. Sorokin signed the search warrants, which were assigned docket numbers 12-MJ-6221 and 12-MJ-6251.

8. On December 16, 2014, a federal Grand Jury sitting in Massachusetts returned a 131-count indictment charging 14 owners, employees, and associates of NECC with a variety of criminal charges in United States v. Barry J. Cadden et al., 14-cr-10363-RGS. Barry J. Cadden ("Cadden"), NECC's owner and head pharmacist at NECC, and Glenn A. Chin ("Chin"), NECC's supervisory pharmacist, were charged with racketeering, in violation of Title 18, United States Code Section 1962, based in part on twenty-five acts of second-degree murder in Florida, Indiana, Maryland, Michigan, North Carolina, Tennessee, and Virginia. Cadden and Chin face a maximum punishment of life imprisonment. The indictment also charges that Cadden, along with four other defendants, conspired to defraud the FDA by purporting to operate NECC as a state-regulated pharmacy, dispensing drugs pursuant to valid, patient-specific prescriptions, rather than as a drug manufacturer distributing drugs in bulk to customers and subject to heightened FDA oversight.

9. The 14 defendants in the criminal case were arraigned on December 17, 2014. Since that date, the USAO has provided the defense with approximately 8.7 million pages of discovery. No trial date is presently set. The prosecution team is actively engaged in extensive pretrial proceedings, including interviewing new witnesses, continuing to review and assess seized documents and evidence, preparing and producing discovery to the criminal defendants, and responding to filings in the criminal case. The USAO anticipates calling multiple FDA witnesses at trial.

Interference with the Criminal Case

10. I am informed that on March 6, 2015, the FDA was served with a notice of deposition and subpoena to testify pursuant to Federal Rules of Civil Procedure 30(b)(6) and 45 in connection with civil lawsuits filed against doctors and clinics in Tennessee ("Tennessee

Clinic Defendants") who administered NECC's drugs to patients. As discussed below, I have been briefed regarding the deposition notice and documents subpoenaed.

11. The Tennessee Clinic Defendants seek a deponent and documents related to: (a) FDA's authority to investigate, inspect, regulate, and take action against NECC prior to the fungal meningitis outbreak; (b) FDA's investigation, inspections, regulation, and actions related to NECC prior to the fungal meningitis outbreak; (c) FDA's cooperation with the Massachusetts Board of Registration in Pharmacy prior to the fungal meningitis outbreak; (d) the information known by the FDA about NECC prior to the fungal meningitis outbreak; and (e) FDA's investigation, inspection of, and action against NECC following the fungal meningitis outbreak.

12. Compliance with the Tennessee Clinic Defendants' notice of deposition to the FDA would interfere with the ongoing criminal case, United States v. Barry J. Cadden et al., 14-cr-10363-RGS. Accordingly, I request that the Court stay the Tennessee Clinic Defendants' deposition request to the FDA pending resolution of the criminal case. As outlined below, a stay protects the public's interest in achieving justice in the criminal case, preserves the integrity of the criminal case, protects the rights of the criminal defendants, and does not unduly prejudice the civil litigants.

13. The criminal activity charged in the criminal case resulted in the deaths of at least 64 individuals and the suffering of more than 687 others. The public deserves a criminal prosecution of the defendants unaffected by civil litigation focused on identical events. The public's interest in a just resolution of the criminal case is and should be paramount. This is particularly true given the fact that the two lead criminal defendants face potential punishments of life imprisonment for their actions.

14. The deposition sought by the Tennessee Clinic Defendants relates to some, if not much, of the same conduct at issue in the criminal prosecution, that is, the FDA's authority, inspection history, and post-outbreak inspection and investigation of NECC. As currently requested, the deposition, pursuant to Fed. R. Civ. P. 30(b)(6), could involve depositions of more than one FDA witness, given the broad topics and subject areas for which a deponent is sought, and these depositions would be given on behalf of the FDA. A compelled deposition of one or more FDA witnesses before the criminal trial would unfairly and unduly burden the USAO's continuing investigation of NECC and the criminal prosecution of the 14 defendants. Because the FDA deposition(s) in this civil matter would be available for use in the criminal matter as prior statements or admissions, the USAO's prosecution team would need to be involved in preparing the FDA deposition witness(es) so that the team is aware of and understands the details of the witness(es)' testimony and how the testimony would relate to presentation of the government's case in the criminal proceeding. The USAO's involvement would also be necessary to ensure the completeness and accuracy of each witness's testimony, thereby reducing the appearance of inconsistencies from one proceeding to the next. But this participation would, in turn, have several burdensome effects on the criminal prosecution. It would interfere with the prosecution team's work in the criminal case, including interviewing new witnesses, reviewing seized documents and evidence, preparing and producing discovery, and conducting pretrial litigation, at a crucial stage of the case. It would also force the USAO now, months before the criminal trial, to prepare its trial strategy in the criminal case and the role and expected testimony of FDA witnesses in that strategic plan. Such preparation now would be difficult as a substantive matter, given the ongoing case development efforts noted in Paragraph 9 above. The deposition(s) would also prematurely and broadly disclose essential elements of the

government's case-in-chief, allowing the criminal defendants to tailor defenses to fit the anticipated proof.

15. Furthermore, conducting a deposition of one or more FDA witnesses now could generate substantial pretrial publicity that could affect the rights of the 14 criminal defendants to a fair trial. The fungal meningitis outbreak was an unprecedented public health crisis, and the USAO's criminal investigation has generated substantial coverage in both the national and local media for more than two years. It is my understanding that the Tennessee Clinic Defendants could potentially use the FDA deposition testimony in more than 140 individual lawsuits against them. In a high-profile matter such as this, it is likely that such widespread use of the deposition testimony will result in leaks and disclosures of the testimony, in whole or part, to the media, inadvertently or otherwise. Premature disclosure about the government's case, including potential witnesses' testimony or details regarding the nature of evidence seized through search warrants, could affect the ability to seat a fair and impartial jury in the criminal case. While a protective order imposing appropriate confidentiality restrictions with respect to the content of the deposition(s), to the extent such restrictions were scrupulously implemented and followed, could potentially address such concerns, it would not eliminate the unfair burden and prejudice to the government in its prosecution of the criminal case otherwise set out in this declaration.

16. In addition, any potential deposition related to FDA's investigation of NECC following the fungal meningitis outbreak (as opposed to earlier) directly implicates investigatory steps taken by FDA-OCI agents in the criminal case. Such deposition testimony might reveal information about the FDA-OCI agents' investigatory actions and potentially could lead to identification of non-FDA witnesses or informants who provided investigative leads or other information to the agents. Disclosure of the identities of these individuals would likely lead to

additional deposition and discovery requests in this civil proceeding, which might well, in turn, provide the criminal defendants with sworn statements by non-FDA government witnesses and prematurely disclose essential elements of the government's case-in-chief. Such an outcome would only compound the unfair prejudice and burden on the government by forcing the USAO to prepare to an even greater extent its criminal trial strategy months before the criminal trial – and to, in essence, present its case-in-chief collaterally in the Tennessee civil proceeding — as well as by further diverting the prosecution team from ongoing case development. Moreover, because the depositions would prematurely and broadly disclose much of the government's case-in-chief, they would further enable the criminal defendants to tailor defenses to fit the anticipated proof.

17. On the other hand, staying the FDA deposition(s) until after the criminal trial would both reduce the burden on the FDA witness(es) and produce some efficiencies in these civil cases because testimony by FDA witnesses in the criminal trial could be used later in the Tennessee Clinic Defendants' civil litigation. As stated above, the USAO anticipates calling multiple FDA witnesses in the criminal trial. Much of the testimony sought by the Tennessee Clinic Defendants will be elicited in the criminal case during the government's case-in-chief. Therefore, postponing the deposition(s) until after the criminal case has concluded is a more efficient use of FDA resources than having parallel duplicative proceedings covering the same topics. Further, following the conclusion of the criminal trial, the Tennessee Clinic Defendants may find they no longer need a deposition from the FDA at all, or instead may need only a more limited deposition focusing on a narrower set of topics.

I declare under penalty of perjury that the foregoing is true and accurate to the best of my knowledge, information, and belief.

Executed on May 8, 2015.

Carmen M. Ortiz

CARMEN M. ORTIZ
UNITED STATES ATTORNEY